UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PETER LIND, LINDA S. WOOD, LUIS A. PARODI, and GABRIEL VOGELI

Appeal No. 2005-0792
Application No. 09/750,373

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 7-10, 12-25 and 29-33, which are all the claims pending in the application.

Claim 25 is illustrative of the subject matter on appeal and is reproduced below:

25. An isolated nucleic acid molecule comprising SEQ ID NO:12.

The references relied upon by the examiner are:

Bork et al. (Bork '96), "Go Hunting in Sequence Databases but Watch out for the Traps," Trends in Genetics, Vol. 12, No. 10, pp. 425-427 (1996)

Doerks et al. (Doerks), "Protein Annotation: Detective Work for Function Prediction," Trends in Genetics, Vol. 14, No. 6, pp. 248-250 (1998)

Brenner, "Errors in Genome Annotation," Trends in Genetics, Vol. 15, No. 4, pp. 132-133, (1999)

Bork (Bork '00), "Powers and Pitfalls in Sequence Analysis: The 70% Hurdle," Genome Reearch, Vol. 10, pp. 398-400 (2000)

Skolnick, "From Genes to Protein Structure and Function: Novel Applications of Computational Approaches in the Genomic Era," Trends in Biotech., Vol. 18, No. 1, pp. 34-39 (2000)

GROUNDS OF REJECTION

Claims 1, 7-10, 12-25 and 29-33 stand rejected under 35 U.S.C. § 101 as lacking utility and § 112, first paragraph, for lack of enablement based on the finding of lack of utility.

We affirm.

CLAIM GROUPING

The claims stand or fall together. Brief, page 2. Since all claims stand or fall together, we limit our discussion to representative independent claim 25. Claims 1, 7-10, 12-24 and 29-33 will stand or fall together with claim 25. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

BACKGROUND

According to the examiner (Answer, page 3), "[a]ppellants disclose in the specification that the claimed receptor is believed to be a G protein-coupled receptor." As set forth in the specification (page 1), G protein-coupled receptors "form a vast superfamily of cell surface receptors which ... bind a variety of

"form a vast superfamily of cell surface receptors which ... bind a variety of ligands ... and are important in the normal (and sometimes the aberrant) function of many cell types." According to appellants' specification (page 2), each G protein-coupled "receptor has its own characteristic primary structure, expression pattern, ligand-binding profile, and intracellular effector system." In this regard, appellants disclose (specification, bridging sentence, pages 2-3), "a need exists for G protein-coupled receptors that have been identified and show promise as targets for therapeutic intervention in a variety of animals, including humans."

According to the specification (page 13), "[t]he present invention provides purified and isolated polynucleotides ... that encode unknown G protein-coupled receptors heretofore termed novel GPCRs, or nGPCRs." Appellants disclose (Specification, page 14), the nucleic acid of SEQ ID NO:12 was detected in brain tissue indicating that the "nGPCR-[1007[1]] protein" encoded by this sequence is a neuroreceptor. The specification, however, also indicates that "significant expression" of the nucleic acid of SEQ ID NO:12 was also "observed in lymph node, thyroid gland, and testis." Specification, page 99. Based on this observation, appellants postulate (Specification, bridging paragraph, pages 99-100) that

> [e]xpression of nGPCR-1007 in these tissues provides an indication that modulators[2] of nGPCR[-1007] activity have utility for treating metabolic diseases (e.g., type 2 diabetes, obesity,

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[1] See Table 1 (specification, page 13), wherein nGPCR-1007 is disclosed to be encoded by SEQ ID NO: 12.

[2] We emphasize that claim 25 is drawn to an isolated nucleic acid molecule comprising SEQ ID NO:12, not a modulator of a protein encoded by SEQ ID NO:12.

> disorders (e.g.[,] thyroitoxicosis, myxoedema); inflammatory conditions (e.g., Chron's disease); rheumatoid arthritis; autoimmune disorders; movement disorders; CNS disorders (e.g., pain including migraine; stroke; psychotic and neurological disorders; including anxiety, mental disorder, manic depression, anxiety, generalized anxiety disorder, post-traumatic-stress disorder, depression, bipolar disorder, delirium, dementia, severe mental retardation; dyskinesias, such as Huntington's disease or Tourette's Syndrome; attention disorders including ADD and ADHD, and degenerative disorders such as Parkinson's, Alzheimer's; movement disorders, including ataxias, supranuclear palsy, etc.); among others.

According to the specification (page 14), the claimed nucleic acid molecule is

> useful for recombinantly expressing the receptor and also for detecting expression of the receptor in cells ... in the design of antisense and other molecules for the suppression of the expression of nGPCR-[1007] in a cultured cell, a tissue, or an animal; for therapeutic purposes; or to provide a model for diseases or conditions characterized by aberrant nGPCR-[1007] expression.

In addition, the specification discloses (page 17), "[p]olynucleotides of the invention may also provide a basis for diagnostic methods useful for identifying a genetic alteration(s) in a nGPCR-x locus that underlies a disease state or states, which information is useful both for diagnosis and for selection of therapeutic strategies."

DISCUSSION

The examiner rejected all of the claims as lacking patentable utility.[3] The examiner bears the initial burden of showing that a claimed invention lacks

[3] The examiner rejected the claims under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph. However the rejection for nonenablement was presented simply as a corollary of the finding of lack of utility. See Answer, page 5. Therefore, although we discuss only the § 101 rejection, our conclusion also applies to the § 112 rejection.

patentable utility. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.").

The seminal decision interpreting the utility requirement of § 101 is Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966). At issue in Brenner was a claim to "a chemical process which yields an already known product whose utility—other than as a possible object of scientific inquiry—ha[d] not yet been evidenced." Id. at 529, 148 USPQ at 693. The Patent Office had rejected the claimed process for lack of utility, on the basis that the product produced by the claimed process had not been shown to be useful. See id. at 521-22, 148 USPQ at 690. On appeal, the Court of Customs and Patent Appeals reversed, on the basis that "where a claimed process produces a known product it is not necessary to show utility for the product." Id. at 522, 148 USPQ at 691.

The Brenner Court noted that although § 101 requires that an invention be "useful," that "simple, everyday word can be pregnant with ambiguity when applied to the facts of life." Id. at 529, 148 USPQ at 693. Thus,

> [it] is not remarkable that differences arise as to how the test of usefulness is to be applied to chemical processes. Even if we knew precisely what Congress meant in 1790 when it devised the "new and useful" phraseology and in subsequent re-enactments of the test, we should have difficulty in applying it in the context of contemporary chemistry, where research is as comprehensive as man's grasp and where little or nothing is wholly beyond the pale of "utility"—if that word is given its broadest reach.

Id. at 530, 148 USPQ at 694.[4]

The Court, finding "no specific assistance in the legislative materials underlying § 101," based its analysis on "the general intent of Congress, the purposes of the patent system, and the implications of a decision one way or the other." Id. at 532, 148 USPQ at 695. The Court concluded that "[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695.

The Court considered and rejected the applicant's argument that attenuating the requirement of utility "would encourage inventors of new processes to publicize the event for the benefit of the entire scientific community, thus widening the search for uses and increasing the fund of scientific knowledge." The Court noted that, while there is value to encouraging disclosure, "a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to

[4] The invention at issue in Brenner was a process, but the Court expressly noted that its holding "would apply equally to the patenting of the product produced by the process." Id. at 535, 148 USPQ at 695-96.

production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development." Id. at 534, 148 USPQ at 695.

The Court took pains to note that it did not "mean to disparage the importance of contributions to the fund of scientific information short of the invention of something 'useful,'" and that it was not "blind to the prospect that what now seems without 'use' may tomorrow command the grateful attention of the public." Id. at 535-36, 148 USPQ at 696. Those considerations did not sway the Court, however, because "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Id.

Subsequent decisions of the CCPA and the Court of Appeals for the Federal Circuit have added further layers of judicial gloss to the meaning of § 101's utility requirement. The first opinion of the CCPA applying Brenner was In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967). The invention claimed in Kirk was a set of steroid derivatives said to have valuable biological properties and to be of value "in the furtherance of steroidal research and in the application of steroidal materials to veterinary or medical practice." Id. at 938, 153 USPQ at 50. The claims had been rejected for lack of utility. In response, the applicants submitted an affidavit which purportedly "show[ed] that one skilled in the art would be able to determine the biological uses of the claimed compounds by routine tests." Id. at 939, 153 USPQ at 51.

The court held that "nebulous expressions [like] 'biological activity' or 'biological properties'" did not adequately convey how to use the claimed compounds. Id. at 941, 153 USPQ at 52. Nor did the applicants' affidavit help their case: "the sum and substance of the affidavit appear[ed] to be that one of ordinary skill in the art would know 'how to use' the compounds to find out in the first instance whether the compounds are—or are not—in fact useful or possess useful properties, and to ascertain what those properties are." Id. at 942, 153 USPQ at 53.

The Kirk court held that an earlier CCPA decision, holding that a chemical compound meets the requirements of § 101 if it is useful to chemists doing research on steroids, had effectively been overruled by Brenner. "There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher' was recognized, and clearly rejected, by the Supreme Court" in Brenner. See Kirk, 376 F.2d at 945, 153 USPQ at 55.

More recently, in In re Ziegler, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993), the Federal Circuit considered the degree of specificity required to show utility for a claim to polypropylene. The U.S. application on appeal in Ziegler claimed priority to a German application filed in 1954. "In the German application, Ziegler disclosed only that solid granules of polypropylene could be pressed into a flexible film with a characteristic infrared spectrum and that the polypropylene was 'plastic-like.'" Id. at 1203, 26 USPQ2d at 1605. "Ziegler did not assert any practical use for the polypropylene or its film, and Ziegler did not

disclose any characteristics of the polypropylene or its film that demonstrated its utility." Id. The court held that the German application did not satisfy the requirements of § 101 and therefore could not be relied on to overcome a rejection based on an intervening reference. See id., 26 USPQ2d at 1606. "[At] best, Ziegler was on the way to discovering a practical utility for polypropylene at the time of the filing of the German application; but in that application Ziegler had not yet gotten there." Id., 26 USPQ2d at 1605.

On the other hand, the CCPA reversed a rejection for lack of utility in In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). The applicant in Jolles claimed pharmaceutical compositions that were disclosed to be useful in treating acute myeloblastic leukemia. See id. at 1323, 206 USPQ at 886. The active ingredients in the compositions were closely related to daunorubicin and doxorubicin, both of which were "well recognized in the art as valuable for use in cancer chemotherapy." Id., 206 USPQ at 887. The applicant also submitted declaratory evidence showing that eight of the claimed compositions were effective in treating tumors in a mouse model, and one was effective in treating humans. See id. at 1323-24, 206 USPQ at 887-88. The court noted that the data derived from the mouse model were "relevant to the treatment of humans and [were] not to be disregarded," id. at 1327, 206 USPQ at 890, and held that the evidence was sufficient to support the asserted therapeutic utility. See id. at 1327-28, 206 USPQ at 891.

The Federal Circuit held in Cross v. Iizuka, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985), that in vivo testing (as in Jolles) was not necessarily required to

show utility in the pharmaceutical context. The Cross court stated that "[it] is axiomatic that an invention cannot be considered 'useful,' in the sense that a patent can be granted on it, unless substantial or practical utility for the invention has been discovered and disclosed where such utility would not be obvious." Id. at 1044, 224 USPQ at 742 (citing Brenner v. Manson). The court "perceive[d] no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, in vitro testing, may establish a practical utility for the compound in question." Id. at 1051, 224 USPQ at 748. Successful in vitro testing could provide an immediate benefit to the public, by "marshal[ling] resources and direct[ing] the expenditure of effort to further in vivo testing of the most potent compounds . . ., analogous to the benefit provided by the showing of an in vivo utility." Id. On the facts of that case – successful in vitro testing supplemented by similar in vitro and in vivo activities of structurally similar compounds – the court held that in vitro activity was sufficient to meet the requirements of § 101. See id.

The Federal Circuit confirmed in In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995), that human testing is not necessary to establish utility for a method of treatment. The invention claimed in Brana was a group of compounds disclosed to have antitumor activity. See id. at 1562, 34 USPQ2d at 1437-38. The specification disclosed that the claimed compounds had higher antitumor activity than related compounds known to have antitumor activity, and the applicants provided declaratory evidence of in vivo activity against tumors in a mouse model. See id., 34 USPQ2d at 1438. The court held that these data

were sufficient to satisfy § 101; usefulness in patent law does not require that the invention be ready to be administered to humans. See id. at 1567, 34 USPQ2d at 1442.

Several lessons can be drawn from Brenner and its progeny. First, § 101's requirement that an invention be "useful" is not to be given its broadest reach, such that little or nothing of a chemical nature would be found to lack utility. See Brenner, 383 U.S. at 530, 148 USPQ at 694. Thus, not every "use" that can be asserted will be sufficient to satisfy § 101. For example, the steroid compound at issue in Brenner was useful as a possible object of scientific inquiry, and the polypropylene claimed in Ziegler was useful for pressing into a flexible film, yet both lacked sufficient utility to satisfy § 101. See Brenner, 383 U.S. at 529, 148 USPQ at 696; Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

Rather than setting a de minimis standard, § 101 requires a utility that is "substantial", i.e., one that provides a specific benefit in currently available form. Brenner, 383 U.S. at 534-35, 148 USPQ at 695. This standard has been found to be met by pharmaceutical compositions shown to be useful in mouse models and in humans for treating acute myeloblastic leukemia (Jolles, 628 F.2d at 1327-28, 206 USPQ at 891); by evidence showing successful in vitro testing supplemented by similar in vitro and in vivo activities of structurally similar compounds (Cross, 753 F.2d at 1051, 224 USPQ at 748); and by evidence showing in vivo antitumor activity in mice, combined with a disclosure that the claimed compounds had higher antitumor activity than a related compound known to have antitumor activity (Brana, 51 F.3d at 1567, 34 USPQ2d at 1442).

By contrast, Brenner's standard has been interpreted to mean that "vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher'" would not satisfy § 101. See Kirk, 376 F.2d at 945, 153 USPQ at 55 (interpreting Brenner). Likewise, a disclosure of a "plastic-like" polypropylene capable of being pressed into a flexible film was held to show that the applicant was "at best . . . on the way to discovering a practical utility for polypropylene at the time of the filing," but not yet there. Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

On this record, the examiner finds (Answer, page 3), "[t]he claimed receptor is what is termed an 'orphan receptor' in the art. The instant application does not disclose the biological role of the claimed protein or its significance." According to the examiner (Answer, page 4), while appellants disclose that the claimed polynucleotide encodes a protein believed to be a GPCR, "no comparison to any known GPCR could be found in the specification." In this regard, the examiner finds (Answer, page 6), "[t]he specification does not characterize the polypeptide encoded by the polynucleotide of the claimed invention. Therefore binding sites, etc. are not identified. Significant further experimentation would be required of the skilled artisan to characterize the protein and search for ligands." Accordingly, the examiner concludes (Answer, page 5),

> the specification fails to teach the skilled artisan the utility of the claimed polynucleotide of SEQ ID NO:12 ... which [is] only believed to ... [encode a] GPCR[ ]. Therefore, the instant claim[is] drawn to a polynucleotide encoding a protein which has a yet undetermined function or biological significance. There is no

> actual and specific significance which can be attributed to said protein identified in the specification. ... To employ a protein [encoded by a polynucleotide] of the instant invention in the identification of substances which bind to and/or mediate activity of the said receptor is clearly to use it as the object of further research....

We agree with the examiner that the specification's disclosure is inadequate to provide a substantial utility for the claimed invention. As the examiner points out (Answer, page 5), the disclosed utilities[5] for the claimed nucleic acid molecule, and the polypeptide encoded thereby, amount to no more than research on the claimed invention itself. Because the specification fails to disclose the biological activity of the protein encoded by the claimed nucleic acids, none of the disclosed utilities that depend on that biological activity could be practiced without the expectation of a great deal of further experimentation. Cf. Answer, pages 6-7. Thus, the specification does not provide a specific utility for the claimed invention, in currently available form.

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[5] As discussed above, the appellants postulate (Specification, bridging paragraph, pages 99-100) that the expression of nGPCR-1007 in the central nervous system, lymph node, thyroid gland, and testis

> provides an indication that modulators of nGPCR[-1007] activity have utility for treating metabolic diseases (e.g., type 2 diabetes, obesity, anorexia, hypertension, atherosclerosis, etc.); and thyroid disorders (e.g.[,] thyroitoxicosis, myxoedema); inflammatory conditions (e.g., Chron's disease); rheumatoid arthritis; autoimmune disorders; movement disorders; CNS disorders (e.g., pain including migraine; stroke; psychotic and neurological disorders; including anxiety, mental disorder, manic depression, anxiety, generalized anxiety disorder, post-traumatic-stress disorder, depression, bipolar disorder, delirium, dementia, severe mental retardation; dyskinesias, such as Huntington's disease or Tourette's Syndrome; attention disorders including ADD and ADHD, and degenerative disorders such as Parkinson's, Alzheimer's; movement disorders, including ataxias, supranuclear palsy, etc.); among others.

In addition, while appellants assert (Brief, page 3) that "the present invention is useful, inter alia, in the diagnosis and treatment of asthma and diabetes," the specification discloses (page 62, emphasis added) only that "nGPCR-x may be useful in the treatment of respiratory ailments such as asthma...."

Notwithstanding the multitude of different diseases which appellants postulate that the claimed polynucleotide and a protein encoded thereby would be useful for treating, appellants' Brief focuses on asthma and diabetes. According to appellants (Brief, page 7[6]), "[t]he specification does teach 'the utility of the claimed polynucleotide of SEQ ID NO: 12 ..., stating that the claimed receptor is useful in the treatment of asthma and diabetes." See also, Brief, page 8, wherein appellants assert the claimed receptor exhibits about 84% sequence identity to G protein-coupled receptor for asthma susceptibility (GPRA receptors) which "play a role in asthma" and "asthma susceptibility"; and arginine vasopressin receptors "which are involved in the 'pathogenesis of asthma and other IgE-mediated diseases' as well as diabetes."

In this regard, appellants argue (Brief, page 4), "BLAST searches show significant similarity between the claimed receptors and known receptors involved in asthma. Highest scoring matches show between about 82% and 84% percent similarity to two isoforms of GPRA receptors (also known as 'G protein-coupled receptor for asthma susceptibility' or 'GPR154')...." In addition, appellants assert (id.), "BLAST searches show significant similarity between the claimed receptors and known arginine vasopressin receptors. Highest scoring matches show between about 82% and 84% percent similarity to a vasopressin receptor (known as "VRR1")...."

We note, however, that this BLAST data is not presented in appellants' originally filed disclosure. Further, as to the nexus between the claimed

[6] Appellants' Brief is not paginated. Accordingly, we have treated the Brief as if it was numbered

polynucleotide (which encodes nGPCR-1007) and asthma, we note that appellants' disclosure, at best, suggests (specification, page 62, emphasis added) that "nGPCR-x may be useful in the treatment of respiratory ailments such as asthma...." What is unclear is which of the 46[7] disclosed sequences for nGPCR-x would be useful for the treatment of asthma. In this regard, we note that "asthma" is not included in appellants' extensive listing (see specification, pages 99-100) of diseases for which the claimed polynucleotide, which encodes nGPCR-1007, is postulated to be associated.

Nevertheless, in support of their arguments relating to the BLAST data, appellants rely on three post-filing date references[8] to support their assertion that GPRA receptors are known to play a role in asthma, and that arginine vasopressin receptors are known to be involved in asthma and diabetes. We, however, decline to consider these post-filing date references, which published in 2004. The instant application was filed December 28, 2000, claiming priority to earlier provisional applications.[9] The utility requirement must be met as of the filing date of the application. See In re Brana, 51 F.3d 1560, 1567 n.19, 34 USPQ2d 1436, 1441 n.19 (Fed. Cir. 1995) ("[e]nablement, or utility, is

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consecutively starting with the first page.

[7] According to appellants' specification (page 16), "[p]referred DNA sequences encoding human nGPCR-x polypeptides are selected from the group consisting of ..." SEQ ID NOs: 1-46.

[8] Laitinen et al., "Characterization of a Common Susceptibility Locus for Asthma-Related Traits," Science, Vol. 304, pp. 300-304 (2004); Thibonnier, "Genetics of Vasopressin Receptors," Current Hypertension Reports, Vol. 6, pp. 21-26 (2004); and "Entrez Gene", http://www.ncbi.nlm.nih.gov/entrez/, Entrez Reference No.: GPR154 (updated September 12, 2004).

[9] According to Table 1, (specification, bridging paragraph, pages 13-14), SEQ ID NO: 12 was originally filed in Provisional Application No.: 60/224, 321, filed August 11, 2000.

determined as of the application filing date.") The references relied upon by appellants were published after the filing date of the application, and appellants have cited no evidence to show that those skilled in the art would have been aware of the relevant disclosures as of the application's filing date.[10] Therefore, these post-filing date references cannot be relied upon to establish the utility of the claimed polynucleotide.

We recognize appellants' assertion (Brief, page 9), "the claimed receptors contain additional functional as well as structural motifs characteristic of arginine vasopressin receptors." According to appellants (Brief, page 10), these "characteristics are described in [the post-filing date reference,] Thibonnier [2004, see supra n. 8]...." However, for the reasons set forth above, we decline to consider this post-filing date reference. Therefore, we find no support on this record to support appellants' assertion (Brief, page 11), "[t]he structural similarities, including both sequence identity and conserved motifs, between the claimed receptors and the known receptors, ... support [a]ppellants' assertion of

[10] In this regard, we recognize appellants' reliance (Brief, page 4) on Shimura et al., "Urinary Arginine Vasopressin in Asthma: Consideration of Fluid Therapy," Acta Paediatr Jpn, Vol. 32, pp. 197-200 (1990), to support the assertion that "the conopressin 2 receptor is an arginine vasopressin receptor...." Shimura et al., however, makes no reference to the conopressin 2 receptor, an arginine vasopressin receptor, or a receptor of any kind. To the contrary, Shimura reports on the observed levels of antidiuretic hormone (ADH) and urinary arginine vasopressin (AVP) in 28 asthmatic patients. Rather than establish any nexus between a receptor, particularly a GPCR, and the observed levels of ADH and AVP, Shimura concludes (page 200), "[f]luid therapy is important for patients with severe asthmatic attacks...." Accordingly, we fail to see the relationship between Shimura and appellants' claimed invention.

utility and would lead the art skilled [sic] to 'conclude that the asserted utility is more likely than not true.'"

For the foregoing reasons, we disagree with appellants' conclusion (id.), "[t]he specification discloses that the claimed receptors are useful in the treatment of asthma and diabetes...." In our opinion, the evidence of record does not support this assertion. Accordingly, we affirm the rejection of claim 25 under 35 U.S.C. § 101 as lacking utility and § 112, first paragraph, for lack of enablement based on the finding of lack of utility. As discussed supra claims 1, 7-10, 12-24 and 29-33 will stand or fall together with claim 25.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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